IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

ACTAVIS'S SUPPLEMENTAL BRIEF

In response to this Court's invitation, the Actavis Defendants submit the following supplemental brief in support of their Motions.

1) Plaintiffs may not rely on allegations that Actavis was a "sloppy" manufacturer of non-Digitek® products as a basis for an inference that Actavis manufactured and released to market out-of-specification Digitek®.[1] Federal courts, applying a variety of different rules, routinely bar the kind of general-to-specific inference that Plaintiffs advocate. For example:

- Federal courts have applied Rule 404 in negligence cases to preclude a plaintiff from using evidence of defendants' past accidents to prove negligence on a specific occasion. *See So. Pacific Transp. Co. v. Builders Transp., Inc.*, No. 90-3177, 1993 WL 185620, at *10 (E.D. La. May 25, 1993) (applying Rule 404(b) to hold that "[e]vidence of the train crew's prior negligent acts is not admissible to prove that its members were negligent on June 11, 1990.") (citing *Jones v. So. Pacific R.R.*, 962 F.2d 447, 449 (5th Cir. 1992) (prior safety record of train conductor not admissible to prove negligence in grade crossing accident)).

- Rule 404 also applies in product liability cases to exclude evidence that relates to a manufacturer's conduct with respect to products other than the product that is the subject of the litigation. *See Mason v. Texaco, Inc.*, 741 F. Supp. 1472, 1504 (D. Kan. 1990) (barring evidence introduced by defendant regarding company conduct with respect to

[1] Defendants' General Background Statement of Key Factual Information Regarding Digitek detailed how few of FDA's 483 observations related to Digitek®. *See* Doc. 522 at 17-20; *see also* Defendants' Reply in Support of Summary Judgment, Doc. 570 at 4-6.

"other products" because "Texaco has been sued in this case only for its conduct with respect to the product benzene, and this conduct may not be established by using character evidence circumstantially for the purpose of proving action in conformity with that character on a particular occasion.").

- And apart from Rule 404, but applying the same policy, federal courts preclude plaintiffs from proving defect with aggregated evidence about products *other* than the one used by the plaintiff. *See, e.g.*, *City of St. Petersburg v. Total Containment, Inc.*, 265 F.R.D. 630, 635-36, 638 (S.D. Fla. 2010) (denying class certification and rejecting "the notion that strict liability . . . could be subject to a clear-cut determination with generalized proof" because "evidence that FlexPipe was generally defective would do nothing to resolve whether the defect did in fact cause any individual class member's harm"); *Dahlgren's Nursery, Inc. v. E.I. du Pont de Nemours and Co., Inc.*, No. 91-8709-CIV, 1994 WL 1251231, at *11-12 (S.D. Fla. Oct. 30, 1994) ("Although generalized proof may be well suited for those cases in which the cause of the damages is 'a single tragic happening,' it is not well suited for those cases in which no one set of operative facts establishes liability and no single proximate cause equally applies to each potential class member.").

2) This Court has already determined that evidence of non-Digitek® production problems is irrelevant to proving whether a specific plaintiff received a defective tablet. *See* PTO No. 27, Doc. 150 at 15; *see also TFWS, Inc. v. Franchot*, 572 F.3d 186, 191 (4th Cir. 2009) ("The law of the case doctrine 'posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'") (citing *United States v. Aramony*, 166 F.3d 655, 661 (4th Cir.1999)).

3) Plaintiffs cannot prove the existence of defective Digitek® by drawing an inference of defect from the fact—if even proven—that a plaintiff experienced harm from digoxin. This position, which Plaintiffs adopted at oral argument (*see* Transcript of 9/14/11 Hearing at 73-76), is an impermissible application of the "malfunction theory" of defect addressed in Defendants' summary judgment briefing. *See* Doc. 524 at 6-7.

- The "malfunction theory" makes sense in cases where the defect inference is simple—for example, where an accident occurs when a truck's newly installed braking mechanism fails. In this sense, it is related to the *res ipsa loquitur* inference. But neither the malfunction theory nor *res ipsa* apply in pharmaceutical cases because of the many ways

in which drugs interact with other factors and because adverse results may occur for many reasons unrelated to defect.

- Regardless, proof of an injury is generally not sufficient to prove product defect. *See Helene Curtis Indus., Inc. v. Pruitt*, 385 F.2d 841, 853 (5th Cir. 1967) ("The cornerstone rule in products liability is that proof of mere injury furnishes no rational basis for inferring that the product was defective for its intended use.")

- And here, Plaintiffs cannot prove a "malfunction"—an excess dose of digoxin—as a matter of law because: 1) it is uncontested that there are reasons for digoxin toxicity or high serum levels other than defect; and 2) Plaintiffs' experts have not taken "serious account" of those other causes.

4) The distinction between evidence of "adulteration" and evidence of "defect" is a legal one, not a semantic one. By focusing on adulteration, Plaintiffs "miss the mark" as to their burden to prove *defective* Digitek® on the market.

- Evidence of adulterated product, standing alone, can never make it "more likely than not" that a plaintiff received a *defective* drug because the standard that the FDA applies to determine whether a drug is adulterated is legally less rigorous than the more-likely-than-not standard applied in civil cases. *See McClain v. Metabolife*, 401 F.3d 1233, 1249-50 (11th Cir. 2005); *see also* Doc. 524 at 11.

- Using the terms adulterated and defective interchangeably is a logical fallacy. While all defective drugs are by definition adulterated, not all adulterated drugs are defective. *See* Doc. 524 at 9-10. Plaintiffs have cited no authority to contest this well-established legal distinction.

5) Plaintiffs' singular focus on the investigation into Batch 70924A undermines their ability to prove that any plaintiff received a defective tablet.

- FDA's criticism of Batch 70924A pertained to how Actavis *investigated* the incident, not the fact that double-thick tablets were produced and caught. In fact, despite its dissatisfaction with the investigation, FDA concluded that the likelihood that double-thick tablets made it to the market was small and that harm to consumers was "very unlikely." *See* FDA Statement, Doc. 522 at 4-5.

- And even if Plaintiffs could infer that double-thick tablets from Batch 70924A evaded detection and made it to market, they have no evidence that any plaintiff received tablets from that batch. Indeed, Batch 70924A involved 0.125 mg tablets; but it is undisputed that both Ms. Rivera-Vega and Mr. McCornack ingested 0.250 mg tablets.

6) The difference between a normal-sized and a double-thick tablet is noticeable to the eye when not obscured by packaging, and of course can be measured outside packaging. Yet the McCornack Plainiff, despite having 90+ remaining untested tablets, has never identified a too-thick tablet. Likewise, it would have been impossible for Ms. Rivera-Vega to receive a double-thick Digitek® tablet because she received her drugs in a "blister pack" (*see Deposition* of Scottie Vega at 31:12-17, attached to Vega Doc. 55 as Exhibit 9), and it is undisputed that a blister pack could at most hold a tablet 10% in excess of its size specifications. *See* Defs' Mot. to Exclude Unreliable Hearsay, Doc. 527 at 2.

7) Plaintiffs' expert witnesses, like Dr. Delgado, cannot infer the existence of a double-thick Digitek® tablet using a differential diagnosis. *See* 9/14/11 Transcript at 205-06. Differential diagnoses are a well-established tool in the Fourth Circuit for proving *causation*, not defect. *See, e.g.*, *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). At most, a reliably conducted differential diagnosis could lead a physician to an opinion that digoxin toxicity caused death, but not an opinion that the toxicity itself was caused by a defective tablet.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2011, a copy of the foregoing **ACTAVIS'S SUPPLEMENTAL BRIEF** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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